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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,006	04/12/2004	Akira Yamamoto	P24816	1571

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
SINGH, SATYENDRA K	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
02/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/822,006	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31* is/are pending in the application.

4a) Of the above claim(s) *32-34,36,37 and 39-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23rd 2007 has been entered.

Claims 1-30 (non-elected invention of group I), 35 and 38 have been canceled by applicant's amendments to the claims.

Applicant's attention is directed to the restriction requirement mailed 9/27/06 which resulted in the election of Group II on 10/27/06 with traverse. Restriction requirement was made final on 1/8/07.

Newly submitted claims 32-34, 36-37, 48-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

> Group II. Claim 31 is directed to **cell culture carriers** (originally, elected invention of group II) to which cells are allowed to adhere to and grow on surface thereof, classified in class 435, subclass 396; other classes and subclasses depending on the components of the cell culture carriers.
>
> Group IV. Claims 32-34, 36, 37, and 48-59 as presented are directed to "in combination, **cell culture carriers** to which cells can adhere to and grow on surfaces thereof, and a **cell culture apparatus** for use with the cell culture carriers" as specifically recited in newly added claim 51; class 435, subclass various depending on the components of said carriers and said apparatus.

NOTE: Claims 48, 50 and 59 recite "**the combination** as claimed in claim 31...", and since, claim 51 has the subject matter i.e. "in combination, cell culture carriers....and a cell culture apparatus...", the instant claims 48, 50 and 59 have been grouped accordingly with the invention of group IV for the purpose of this office action.

Inventions are distinct each from the other because of the flowing reasons:

1. Elected invention of Group II, claim 31 and newly presented invention of Group IV, claims 32-34, 36, 37, and 48-59 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of non-elected apparatus of Group III and Group II requires granular cell culture carriers. The subcombination of Group II is not necessarily granular and has separate utility such as in processes for immobilization and separation of macromolecules and/or living cells. See MPEP § 806.05(c).

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, instant claims 32-34, 36, 37, 39-59 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 31 (originally elected invention of group II; cell culture carriers having magnetic particles) is examined on its merits in this office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 31 (as currently amended) is rejected under 35 U.S.C. 103(a) as being unpatentable over Starling et al (US Patent 6,210,715 B1; [A]) taken with the disclosure of Kitano et al (US Patent 5,540,995; [B]) in view of Nilsson et al (GB 2,093,040A, published as WO 82/00660; IDS).

Claim 31 is directed to **cell culture carriers** to which cells can adhere to and grow on surfaces thereof, each of the cell culture carriers comprising: **a magnetic particle** having **a base body** having a surface, the base body being **formed by** compounding a **resin material** and a magnetic material so that the magnetic material is dispersed in the resin material; and **a coating layer** containing a **calcium phosphate-based compound**, the coating layer being provided to cover at least a part of the surface of the base body of the magnetic particle so that the cells can adhere thereto.

Starling et al [A] teach various cell culture carriers to which cells are allowed to adhere to and grow on surfaces thereof, wherein each of the carriers comprise glass or polymeric (such as polystyrene, polyethylene, dextran, gelatin, and/or glass) beads (suspendable or non-suspendable microspheres; solid or hollow; see Starling et al, abstract, summary of the invention, figures 1-1 and 1-2, column 10, 1st paragraph, in particular) that can be coated with a layer of calcium phosphate-based compound (CaP, such as hydroxyapatite, tricalcium phosphate, or other CaPs; see Starling et al, column 4, lines 1-3, in particular) to cover at least a part of the surface of the microspheres so that the cells are allowed to adhere thereto (also see Starling et al, examples 1-7, example 3 in particular); wherein the cell culture carriers have an average particle size in the range of 100 microns to 6000 microns, wherein the density of the carriers is in the range of 1.2 to 2 g/cc (which can be varied depending on the components of the microbeads and various desired applications; see Starling et al, column 3, lines 47-50, and examples 1-13, in general); wherein the coating layer is formed from porous particles of calcium phosphate-based compound using suitable processes such as spray granulation or disk pelletization (that are well known in the art; see Starling et al, column 16, last paragraph, in particular), and are sintered such that the porous fine particles of CaP-based compound are partially embedded onto the surface of the polymeric microbeads (see Starling et al, examples 3-4, in particular), and provide increased surface area for greater activity in cell culturing applications (see Starling et al, column 17, lines 2-8, in particular).

Kitano et al [B] teach granular polymer composites (average particle size within the range of 1.2 to 30 microns; see abstract, summary of the invention, examples 1-7, and claims, in particular) comprising polymer beads (thermoplastic resins such as nylon, polystyrene, PMMA or polyethylene; see column 3, 2nd paragraph, in particular) having coated on the surface thereof a calcium phosphate-based compound (such as hydroxyapatite; see Kitano et al, column 3, last paragraph, in particular) such that the microcarriers or microbeads are suitable for allowing cells to adhere onto their surface (and thus suitable for the cell culture and/or related medical and diagnostic applications); wherein the coating layer is formed of fine, porous CaP particles that are partially embedded/penetrated into the polymeric microbeads at the vicinity of the surface thereof (see Kitano et al, column 2, lines 10-16, in particular) using a process that requires colliding porous CaP particles to the surface of the polymeric microbeads or microspheres (using Nara Hybridization system; see Kitano et al, column 5, 2nd paragraph, and examples 1-7, in particular); and wherein the density of the composite microcarriers range within 0.9 t o 1.2 g/cc (see Kitano et al, column 3, lines 39-47, in particular).

However, a cell culture carrier comprising **a magnetic particle** in combination with a polymeric resin material, having a surface that can be coated with **CaP-based compound** (as recited in the instant claim 31), is not explicitly disclosed by the teachings of Starling et al taken with Kitano et al.

Nilsson et al (IDS) teach cell culture carriers (microcarriers, suitable for use in the immobilization and cultivation of anchorage-dependent animal cells in and on the surface of the carriers; see Nilsson et al, WIPO document, abstract, page 1, 1st

paragraph, in particular) comprising a magnetic particle (consisting essentially of a ferrite, Fe_3O_4) having a surface, and a coating layer of gelatin or chitosan polymers (that can be cross-linked for improving mechanical strength of the microcarrier beads), and wherein the carriers have a particle size in the range of 100 to 250 μm (see Nilsson et al, pages 10-11, and claims, in particular). In addition, Nilsson et al disclose the general benefits of incorporating magnetic particles (such as Fe_3O_4) in the microcarriers (i.e. cell culture carriers) in order to permit the use of an external magnetic field in order to stir, suspend, and/or isolate the microcarriers (see Nilsson et al, abstract, and page 5, 2nd paragraph, in particular).

Given the detailed disclosure in the cell cultivation art, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to incorporate magnetic particles (as taught by Nilsson et al) into the polymeric microbeads or cell culture carrier composition of Starling et al taken with Kitano et al such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof.

A person of ordinary skill in the art would have been motivated to modify the composition of Starling et al (taken with Kitano et al) by incorporating the magnetic particles in the microbeads, because Nilsson et al discloses the benefits of incorporating magnetic particles (such as Fe_3O_4) in the microcarriers in order to permit the use of an external magnetic field to stir, suspend and/or isolate the microcarriers (see Nilsson et al, abstract, and 2nd paragraph, in particular).

One of ordinary skill in the art would have had a reasonable expectation of success in modifying the cell culture microcarriers of Starling et al (taken with Kitano et al) using the teachings of Nilsson et al as they explicitly disclose the process of making such microcarriers (that are suitable for cell culture applications) by incorporating Fe_3O_4 particles in cross-linked gelatin or chitosan beads or microcarriers (see Nilsson et al, pages 10-11, in particular). In the absence of any evidence to the contrary, an artisan of ordinary skill in the cell cultivation art would have had a reasonable expectation of success in modifying the carriers as disclosed by Starling et al taken with Kitano et al (and in view of Nilsson et al) because all the components (and the method steps required to make such modification), and motivation for such modification are fully provided in the cited prior art references (when taken in combination), as discussed above.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the cell culture art at the time the claimed invention was made.

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 31 (as currently amended) is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claim 10** of copending Application No. 11/190,868 (common inventor and same assignee, PENTAX Corporation, Tokyo, Japan). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the co-pending application are also directed to **a cell culture carrier** having a surface to which cells are allowed to adhere and grow, which is mainly made of a **resin** material (in the form of a base body) that can comprise a **magnetic** material, and the surface of said carrier can be coated with a **calcium phosphate**-based compound (albeit, in which a part of calcium is deficient). Since, calcium deficient hydroxyapatite materials are known in the art to be closure to the natural bone matrix composition, and since the cell adhesion property can be regulated by the ratio of Calcium and phosphate (Ca/P) in compounds such as hydroxyapatite (that are routinely used as a coating material for cell culture

microcarriers in the cell cultivation and immobilization art; see disclosures of Starling et al, or Kitano et al), one of ordinary skill in the clinical art would have been motivated, and would have had a reasonable expectation in substituting an alternative calcium phosphate-based compound (i.e. an art-recognized functional equivalent) for the benefit of controlling the cell-adhesive property of the cell culture carriers. The two sets of claims are clearly co-extensive in scope, and therefore, an obviousness-type double patenting rejection is proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed with the office on October 23rd 2007 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record.

Regarding the 103(a) rejection of claim 31, applicants argue the following (see remarks, pages 10-12, in particular) :

> "Applicants submit that the question is not whether the prior art discloses parts of Applicants' claimed subject matter, but whether one having ordinary skill in the art following the prior art utilized in the rejection would arrive at Applicants' claimed subject matter following the prior art. Under the present circumstances, one having ordinary skill in the art would not arrive at, as recited in Applicants' independent claim 31, cell culture carriers to which cells can adhere to and grow on surfaces thereof, each of the cell culture carriers comprising a magnetic particle having a base body having a surface, the base body being formed by compounding a resin material and a magnetic material so that the magnetic material is dispersed in the resin material; and a coating layer containing a calcium phosphate-based compound, the coating layer being provided to cover at least a part of the surface of the base body of the magnetic particle so that the cells can adhere thereto.
> The Examiner's attention is once again directed, for example, to Applicants" originally filed specification, at page 5, last paragraph, wherein it is disclosed that:
> Further, in this embodiment, it is preferred that each of the magnetic particles is formed by compounding a resin material and a magnetic material. According to this method, it is possible to adjust a density (specific gravity) of the magnetic particle (consequently, the cell culture carrier)

> by setting compounding ratio (mixing ratio) between the resin material and the magnetic material appropriately. Further, the shape and size of the cell culture carrier can also be adjusted easily. Still further, reference is once again made to Applicants' originally filed specification beginning at page 36, penultimate for further description of the preferred magnetic particle being formed of a composite material which is obtained by compounding a resin material and a magnetic material.
> Applicants submit that the Office Action fails to provide sufficient arguments to combine Starling or Kitano and Nilsson, including why these documents should be combined to arrive at the presently claimed subject matter.
> For example, as once again stated in the Office Action, both of the primary documents of Starling and Kitano fail to disclose a cell culture carrier comprising a magnetic particle. Moreover, while the Office Action submits that the secondary document of Nilsson discloses magnetic particles, there is no reason to arrive at Applicants' recited subject matter following any combination of these documents.
> Thus, Applicants respectfully submit that the reasoning set forth in the Office Action, i.e., "such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof" is insufficient motivation to establish a prima facie case of obviousness for the combination recited in Applicants' claim 31."

In response, it is noted that applicants seem to be argue that there is no motivation in the prior art as cited by Examiner, for an artisan of ordinary skill to combine the teachings that are disclosed by Starling et al, taken with Kitano et al in view of Nilsson et al (as relied upon in the obviousness rejection of record) in order to arrive at the invention of cell culture carriers as claimed. On the contrary, as pointed out earlier in the final rejection of record, the cited prior art references (Starling et al taken with Kitano et al, in view of Nilsson et al) relied upon by the Examiner in the obviousness rejection of record (see also discussion above) disclose various cell culture carriers (in the form of microbeads, or microcarriers; suitable for attachment of cells and for anchorage-dependent cell cultivation) that can be formed of polymeric beads (such as resin materials), and can be coated with porous, calcium phosphate-based compound, that can be further modified (in view of the explicit disclosure of Nilsson et al) to include a magnetic material such as ferrite (because Nilsson et al disclose the benefits of incorporating such magnetic particles in the microcarriers, for example,

permitting the use of external magnetic field to stir, suspend and/or isolate the microcarriers, etc.; see Nilsson et al, abstract, and page 5, 2nd paragraph, in particular). Since, all the elements of the claimed invention are fully disclosed in the prior art including the process of compounding a resin material or polymeric beads with porous CaP particles (see Kitano et al, use of Nara Hybridization system to incorporate a coating layer of CaP; column 5, 2nd paragraph, and examples 1-7, in particular) that can be likewise used by an artisan of ordinary skill in the cell cultivation art for incorporating the magnetic material, and thus for successfully modifying the cell culture carriers that are disclosed by Starling et al (taken with Kitano et al). In the absence of any evidence to contrary, the cell culture carriers disclosed by the prior art references (Starling et al taken with Kitano et al, in view of Nilsson et al) meet all the limitations of the instant invention as claimed, and therefore, the obviousness rejection of record over the pending claims is proper.

Regarding the ODP rejection of record, applicant's argument (see remarks, page 14, in particular) is not found to be persuasive because, the scope of claim 10 in the co-pending application Sr. No. 11/190,868 (from the same assignee, having common inventor) is deemed to be co-extensive as discussed above, and thus the ODP rejection of record is properly maintained.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
Patent Examiner
Art Unit 1657

IRENE MARY
PRIMARY EXAMINER